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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,587	03/21/2002	Tsutomu Okubo	1422-0520P	4925
2292	7590	08/06/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			BERKO, RETFORD O	
			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 08/06/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,587

Applicant(s)

OKUBO ET AL.

Examiner

Relford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/20/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgement: The Preliminary Amendment filed March 21, 2002 and the Information Disclosure Statements filed June 21, 2002 and March 17, 2004 are acknowledged.

Status of Claims

Claims 1-15 are pending following applicant's amendment.

The first non-final office action previously mailed to applicant is hereby withdrawn in consideration of the phone interview discussion between examiner and Attorney Schroeder (Please, see Interview Summary herein attached). The first non-final office action did not address all the fifteen (15) claims and therefore the present office action addresses the inadvertent omission.

Claim Objections

Claims 5, 6, and 7 are objected to under 37 CFR 1.75c as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. Accordingly, the claims 5, 6 and 7 are not been further treated on the merits.

Claims included in the prosecution are 1-4 and 8-15.

Claim Rejections-35 USC Sec 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while arguably enabling for regulating the desire for smoking or otherwise suppress craving for nicotine, does not reasonably provide enablement for the prevention of smoking. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with the claim.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C., first paragraph, have been described in *In re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (a) the nature of the invention; (b) the state of the prior art; (c) the relative skill of those in the art; (d) the predictability of the art; (e) the breadth of the claims; (f) the amount of direction or guidance presented (g) the presence or absence of working examples; and (h) the quantity of experimentation necessary.

(a) the nature of the invention: Claim 2 is drawn toward a method for prevention, alleviating or eliminating withdrawal symptoms of smoking.

(b) the state of the prior art: smoking cessation methods or programs are generally known in the art.

(c) the relative skill of those in the art: the relative skill of those practicing the art of prevention and treatment of tobacco use is high to moderate

(d) the predictability of the art: the examiner takes the position that it is highly uncertain to predict the prevention of smoking as the art is generally directed toward behavior change and as such unpredictable because many complex social, economic and psychological factors are involved.

(e) the breadth of the claim: the claim for the prevention of smoking is very broad; the examiner takes the position that the mode of administration overbroad and the specification does not support the breadth of the claims because as previously mentioned, behavior change is a complex

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phenomenon and as such unpredictable due in part to the social, economic and psychological factors that are involved.

(f) the quantity of experimentation necessary: given the state of the art in the prevention of smoking, a person skilled in the art would be burdened with undue “painstaking experimentation study” in order to determine the necessary events bearing on prevention of smoking because of the behavior modification involved as to justify the claims. No guidance is provided in the specification regarding the quantity of experimentation.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8-11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rejected because of the use of the word “prohibition” in the claim. A method cannot prohibit an individual to stop smoking as the use of the method is deemed a voluntary act only. Applicant is advised to modify the claims by substituting another non-compelling word for the word “prohibiting” in the claim.

Claim Rejections-35 U.S.C. 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 15 is directed toward the use of theanine for preparing a medicament for preventing, alleviating or eliminating symptoms caused by prohibition or moderation of smoking, but, since the claim does not set forth any steps involved in the method/process, it is

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unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 1, 2, 3 and 4 are rejected under 35 USC 102(b) as anticipated by Moroe et al (US 4, 634, 588).

The claims are directed toward a composition comprising theanine, said composition for suppressing craving for smoking characterized as withdrawal symptoms caused by prohibition or moderation of smoking.

Patent '588 teaches a chewing gum composition comprising theanine (col 2, lin 1-14 and col 12, lin 62-65).

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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2. Claim 1, 2, 3 and 4 are rejected under 35 USC 102(a) as anticipated by Blum et al (US 6, 132, 724)

Blum et al (Patent '724) teaches a composition comprising theanine. Patent '724 teaches that the composition in appropriate cocktail is useful for the treatment of various disorders in humans known as "Reward Deficiency Syndrome disorders, RDS"; such disorders including tobacco use (col 21, lin 52-55).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-15 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Blaum et al (US 6, 132, 724).

The claims are drawn toward a method of administering a composition comprising theanine (also known as gamma-glutamyl ethylamide) to a patient, such method for eliminating or moderating the withdrawal symptoms of smoking. The claims are also drawn the method of moderating smoking behavior by administering the composition to humans, said method is for suppressing craving for nicotine, alleviating or eliminating withdrawal symptoms. According to the claims, the composition is in a formulation suitable for absorption via the oral mucosa and is suitable as a food composition item or substance.

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Blum et al (Patent '724) discloses a composition comprising theanine (col 75, lin 20-40). Blum et al disclose that the composition is used for the treatment of various disorders in humans known as "Reward Deficiency Syndrome disorders, RDS ". According to Blum, such disorders include tobacco use (col 21, lin 52-55).

Although Blum et al do not specifically disclose the use of theanine for smoking cessation, since according to Blum et al RDS disorders include smoking disorders, it would have been obvious to one of ordinary skill in the art to use theanine for smoking with a reasonable expectation of success. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made based upon the teaching and guidance provided by Blum et al.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Re: AB

GSK
Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600
FW TK Page